Docket No: 09496/0200199-US0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Yoshihiro Mori and Takayuki Oishi

Serial No.: 10/713,772 Art Unit: 3761

Confirmation No.: 8762

Filed: November 14, 2003 Examiner: Pamela L. Craig

For: BLOOD PURIFICATION DEVICE

DECLARATION OF YOSHIHIRO MORI
PURSUANT TO 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
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I, Yoshihiro Mori, declare as follows:

1. I am a citizen of the Japan and over 21 years of age. I was awarded a Doctor of Engineering degree in Mechanical Engineering by the Tokyo Institute of Technology in 1996. I have been employed by Nikkiso Co., Ltd. of Makinohara, Japan since 1996 as s design engineer of medical devices. My present responsibilities include the design of biological information monitors of dialysis devices. I have extensive experience in the field of medical product engineering. I have particular expertise in the field of dialysis products..

2. I am a co-inventor of the invention disclosed by the present application, and make this declaration in support of the this application.

3. I have reviewed the Office Action mailed by the U.S. Patent & Trademark Office on May 27, 2009 for this application. I understand that the pending claims stand

rejected as being unpatentable over Brugger et al. (US 6,554,789, "Brugger"). I have reviewed and am familiar with the disclosure of Brugger.

4. Brugger discloses a layered fluid circuit for use, for example, in a hemofiltration (dialysis) machine as depicted in FIG. 11 of Brugger. It is my understanding that, similar to my invention, the machine disclosed by Brugger includes arterial and venous blood circuits, a blood pump, a blood purifier (dialyzer), and sensors disposed in each of the arterial and venous blood circuits for measuring hematocrit values. It is also my understanding that Brugger discloses an ultrafiltration pump provided in the dialyzer which may be controlled to facilitate the removal of waste fluids at a prescribed waste fluid flow rate, and at least suggests in its description of fluid management and safety features that the machine includes a control unit capable of making calculations based on various sensor values, evaluating calculated and sensed measurement values, and reporting trouble conditions. I further understand that Brugger discloses that that the blood pump may be controlled to provide a prescribed blood flow rate.

5. In the Office Action of May 27, the Examiner suggests that Brugger teaches a machine that is capable of detecting and reporting leaks in the blood circuit. It is my understanding that Brugger discloses a blood leak detector 128 for this purpose, which is distinct from the sensors disposed in each of the arterial and venous blood circuits for measuring hematocrit values. The Examiner also suggests that Brugger teaches that the machine is capable of detecting and reporting malfunctions in at least one of the blood pump and blood purifier (for example, in the ultrafiltration pump). It is my understanding that Brugger discloses that such pump malfunctions are detectable through the operation of various valves and pressure sensors, which are distinct from the sensors disposed in each of the arterial and venous blood circuits for measuring hematocrit values.

6. It is my understanding the Brugger in particular discloses that a rate of the blood pump may be controlled by sensing arterial blood pressure at a predetermined control

point. In my experience, a pressure sensor is often provided for this purpose in an arterial drip chamber, and is used for example to sense unusual pressures resulting from blood coagulation, and not for detecting a blood pump failure. In my experience, pressure sensors may also be provided in the venous blood circuit to circuit failures due to blood coagulation, bent tubing and the like. In this case as well, in my experience, such sensors have not been provided for detecting a blood pump failure.

7. In my experience, a fluid pressure sensor is also commonly provided in the outlet path of ultrafiltration pumps. Such sensors are often coupled with pressure sensors in the fluid inlet path to the dialyzer in order to maintain a balance between inlet and outlet pressures. In my experience, such sensors are not provided for specifically detecting an ultrafiltration pump failure.

8. It is my understanding that Brugger teaches detecting hematocrit values in the arterial and venous blood lines as a means for deriving an actual blood fluid reduction ratio, and controls a flow restrictor in the venous blood circuit to adjust the actual blood fluid reduction ratio to reach a desired blood fluid reduction ratio. This is described, for example, at Col. 24: 21 – 33 of Brugger. As acknowledged by the Examiner in the Office Action of May 27, Brugger does not expressly teach a system that evaluates hematocrit values for the purpose of detecting a malfunction of the blood pump or the ultrafiltration pump.

9. As described in the "Discussion of the Related Art" section of my application with reference to Japanese laid open patent publication number HO-149935, dialyzers at the time of the present invention were known to employ sensors to measure hematocrit (blood concentrations) before and after dialysis. A theoretical blood concentration after dialysis could be calculated as a function of the actual blood concentration before dialysis, the actual blood flow rate of the blood pump and a desired water removal rate of the dialyzer. As noted above, Brugger for example teaches that the blood flow rate can be adjusted (for example, by means of a flow restrictor in the venous blood circuit) to achieve a desired water removal rate for the

dialyzer by comparing the desired rate with measured rate derived from blood concentration values before and after dialysis.

10. In my experience, no dialyzers commercially available as of the time of the present invention incorporated a monitoring device that was operable to detect a malfunction of the blood pump or the ultrafiltration pump by monitoring hematocrit values and evaluating whether the ratio of values measured in the arterial and venous blood lines deviated from a theoretical ratio determined as a function of a preset blood flow rate and a preset water removal rate. Rather, at this time, pump operation was monitored by using a system of pressure and leak sensors. This approach is clearly advocated, for example, by Brugger as described at Col. 10: 10 – 24 and 41 - 47, and at Col. 24: 36 – 45. Notably, this approach suffers the disadvantage of being performed in large part only prior to the start of dialysis, rather than continuously during the operation of the dialyzer.

11. In my experience, it was understood in the art at the time of the invention that it was difficult to adequately control a blood flow rate by simply setting a pumping rate for a blood pump. For example, Brugger at Col. 24: 21 – 34 discloses an adjustable flow restrictor in the venous blood line to assist in controlling the blood flow rate. In presently working to commercialize my invention, it has in fact been difficult to develop an inexpensive, commercially-producible blood pump with adequate sensitivity for controlling the rate of blood flow. In my opinion, one skilled in the art at the time of the present invention would have believed that detection of pump malfunctions could only be practically achieved by using a conventional system of pressure and leak sensors, and would not have judged a blood purification device employing my invention to be practicable.

12. My invention is directed to a dialyzer designed for home use. As result, it is important for the dialyzer to be inexpensive, easy to use, and fail-safe. My invention provides significant benefits in this regard by eliminating the need for the patient to determine a pre-treatment blood concentration before beginning dialysis, thereby saving time and patient

discomfort (see, e.g., page 6, lines 1 - 14 of my specification). In addition, my invention provides a means for monitoring against a malfunction of the blood pump and/or the blood purifier during dialysis, thereby enabling home caregivers to quickly identify potentially serious troubles and halt treatment until further investigated by experienced medical staff. In my opinion, this capability provides a significant improvement over commercial dialyzer systems available prior to the time of my invention.

13. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the instant application or any patent issued thereupon.

15/10/2009
Date

Yoshihiro Mori
Yoshihiro Mori